

## **REMARKS**

Applicants thank Examiners Gross and Low for the very helpful telephonic interviews on December 23, 2009 and January 20, 2010 with Applicants' representatives, Laura Coruzzi and Jacqueline Benn. During the interviews, the written description support for new claims 169-175 was discussed, as well as the obviousness type double patenting rejection in view of U.S. Patent No. 5,876,727 (the "'727 patent"). Examiners Gross and Low indicated during the January 20, 2010 interview that they were satisfied that claims 169-175 were supported by the instant specification and that the claims were patentably distinct from the claims of the '727 patent. Applicants have presented claims 169-175 simply to clarify the claimed invention in accordance with the Examiners' suggestions. Applicants have canceled claims 161-168 without prejudice solely to expedite allowance of the instant application. Applicants also discussed with the Examiners that claims 125, 126, 128, 131-138, and 142-160 have been canceled by this Amendment, and have been transferred to applicants' co-pending Application No. 11/472,215, which has been terminally disclaimed over the co-owned '727 patent, rendering the obviousness-type double patenting rejection of the transferred claims moot. Allowance of amended claims 125, 126, 128, 131-138, and 142-160 is being sought in co-pending Application No. 11/472,215.

### **AN EARLY ALLOWANCE OF CLAIMS 169-175 IS REQUESTED**

Claims 169-175 specify a species within the genus encompassed by the transferred claims 125, 126, 128, 131-138, and 142-160, and are free of the prior art of record for the very same reasons that the transferred claims 125, 126, 128, 131-138, and 142-160 were found to be free of the prior art of record.

### **Claims 161-175 Are Fully Supported by the Instant Specification**

The presented claims directed to compositions of nicotine and pseudomonas exotoxin conjugated via a linker comprising CJ 7.1, wherein Q is another branch identified by its CJ reference number (claim 169, dependent claim 171 further specifies that second branch is CJ 3); or conjugated via a linker comprising CJ 1, wherein Q is another CJ reference number (claim 170, dependent claim 172 further specifies that the second branch is CJ 11) are fully supported by the instant specification under 35 U.S.C. § 112. Applicants invite the Examiner's attention to U.S. Publication No. 2005/0124061 (the "'061 publication", the

publication of the instant application) which fully supports the pending claims. In particular, paragraphs [0062] and [0078] of the '061 publication sets forth that the hapten of the conjugate may be nicotine. (Note: *see* lines 17-20 of paragraph [0062]. Paragraph [0083] of the '061 publication sets forth that the hapten may be conjugated to a suitable carrier, and paragraph [0085] specifies that an example of a suitable carrier is pseudomonas exotoxin.

As far as the linkers or branches that may be used to conjugate the two, Applicants are not picking and choosing from the specification to arrive at the claimed linkers. Rather all of the selections for the linkers are set out in one paragraph (*see, i.e.*, paragraph [0110]) and the ensuing paragraphs [0111 to 0123] describe the selections for Q as set out in paragraph [0110]. Specifically, paragraph [0111] provides that with respect to the branches described in paragraph [0110], n is an integer, preferably selected from about 3 to about 20, however Figures 3B, 4 and 18B provides multiple examples where n=0, n=1 and n=2. Paragraph [0123] provides that Q may be another branch identified by its CJ number and Figures 2A, 3B and 4 provide examples where two branches were combined to form one branch. For instance, Figure 2A provides examples where CJ 1 is combined with another branch. Figure 3B further specifies that when the branch is CJ 1, n can be 1. Claims 169 to 175 further specify that Y is NH. Examples of Y being NH are found in Figure 18B (Examples PS-59 and PS-40). Applicants respectfully submit that claims 169-175 are fully disclosed throughout the specification and therefore supported under 35 U.S.C. 112.

#### **Claims 169-175 Are Not Obvious in View of the Claims of the '727 Patent**

Applicants respectfully submit that claims 169-175 are not obvious over the claims of the '727 patent, alone or in combination, with Green. Claims 169-175 are directed to nicotine conjugated to pseudomonas exotoxin – in particular nicotine modified to further comprise the CJ 1 branch or the CJ 7.1 branch, wherein n is an integer having a value equal to 0, 1 or 2, and Q is another branch identified by its CJ number.

The '727 patent claims do not specify that: (1) pseudomonas exotoxin is the carrier, (2) Q is another branch identified by its CJ number, nor that (3) n is an integer having a value of 0, 1 or 2. These three elements are missing from the claims of the prior art. This defect is not cured by the disclosure of the '727 patent or the secondary reference, Green. Therefore, Applicants respectfully submit that *prima facie* obviousness as to claims 169-175 should not be found.

For the foregoing reasons, Applicants respectfully assert that claims 161-175 are patentable over claims 1-18 of the '727 patent, alone or in combination, with Green.

**CONCLUSION**

Applicants respectfully request that the Examiner consider the amendments and the remarks made herein, and that the Examiner enter them into the record for the present application. An early allowance of claims 169-175 is earnestly sought. The Examiner is invited to contact the undersigned attorney if a telephone call could help resolve any remaining items.

Respectfully submitted,

by *Jacqueline Benn*  
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